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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/746,670

12/22/2000

Shanta M. Modak

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10/02/2006

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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/746,670	<b>Applicant(s)</b> MODAK ET AL.	
	<b>Examiner</b> Carlos A. Azpuru	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 12, 13 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 12, 13, 17-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>01262006</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt is acknowledged of the request for continued examination and information disclosure statement filed 01/26/2006.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 refers to a "...mixture consisting essentially of...". This fails to particularly point out that this is the "**antimicrobial** mixture" of the coating. Correction of the above would parallel claim language found in the other independent claims.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1615

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10, 17, 20-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 8-19 of U.S. Patent No. 6,872,195 (US'195). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'195 claims a medical article which is treated with a solution comprising chlorhexidine which consists essentially of a mixture of chlorhexidine free base and a chlorhexidine salt (see claim 1). The article may be made up of a hydrophilic polymers (see claims 8 and 9). The article may be a catheter (claim 11). The method of preparation involves coating the article in the solution of chlorhexidine and a solvent such as tetrahydrofuran, water or reagent alcohol, allowing sufficient time for the article to swell. In other words, the coating may comprise a hydrogel. The treatment solution may comprise 1-5% chlorhexidine (claim 2). While US'195 does not set out the percentage of chlorhexidine salt to chlorhexidine free base, or the exact ratio of solvent components, the reference clearly claims the inventive concept of using the combination of chlorhexidine free base and chlorhexidine salt in combination to treat a catheter. The ratios of each can be modified to the instantly claimed parameters without undue experimentation as a means of optimizing the antimicrobial properties of the catheter coating as taught by US'195. The duration of soaking can also be easily modified. Antimicrobial activity would be a function of the

compounds used and the method of preparation. As such, those of ordinary skill would have expected similar antimicrobial properties from the instantly claimed catheter and its method of preparation, given the claims of US'195. There are no unusual and/or unexpected results which would rebut prima facie obviousness. The instantly claimed invention would have been obvious to one of ordinary skill in the art at the time of invention given the claims of US'195.

Claims 1-8, 10, 12, 13, 17-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-63 of copending Application No. 10/600,257 (US'257). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'257 claims an antimicrobial medical article comprising a mixture of chlorhexidine free base and chlorhexidine salt in a weight/weight ratio of between 1:1 and 1:5 (claims 1, 11). Solvent mixtures are listed at claims 7-9, 12-15.. The chlorhexidine salt is set out as chlorhexidine diacetate in claims 10, 16, 24, 31. The article is identified as a catheter in claim 58. The duration of soaking can also be easily modified. Antimicrobial activity would be a function of the compounds used and the method of preparation. As such, those of ordinary skill would have expected similar antimicrobial properties from the instantly claimed catheter and its method of preparation, given the claims of US'257. There are no unusual and/or unexpected results which would rebut prima facie

Art Unit: 1615

obviousness. The instantly claimed invention would have been obvious to one of ordinary skill in the art at the time of invention given the claims of US'257.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

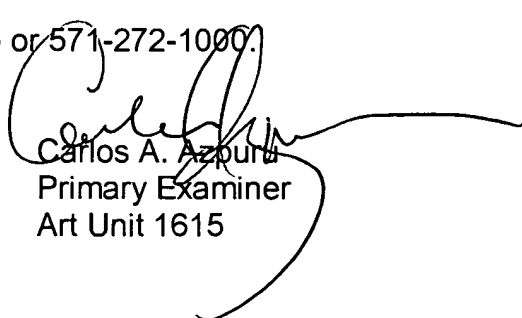
US 6,626, 873 is cited as a patent of interest in its disclosure of a hydrophilic polymeric medical comprising a hydrophilic polymer, chlorhexidine free base, chlorhexidine salt, and triclosan. Triclosan would be excluded from the instant antimicrobial mixture because of the "consisting essentially of" language found in the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpuru  
Primary Examiner  
Art Unit 1615

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